ANODIA SYSTEMS

Dr. Thad Overmyer
514 South Third Street
Danville, Ky 40422
Phone: 1-866-246-2548
Fax: 1-866-926-8246

JUN 1 9 2003

K023896

"Premarket Notification 510{k} Summary"

1. Submitter:

   November 12, 2002
   Dr. Thad Overmyer
   514 South Third Street
   Danville, Kentucky 40422
   Tel: 859-236-4778
   Fax: 859-236-9136

2. Name of Device
   A. Trade Name—C-1890
   B. Common name—Pressurized bottle system
   C. Classification Name: Unit, Operative Dental

3. C-1890 is compared to the Class I device K962665 A-Dec Self-Contained Water System

4. The C-1890 is a pressurized bottle system capable of supplying a solution or pressurized air to the dental unit water lines. The system can be used with solutions to clean the dental unit waterlines by air purging the waterlines and/or injecting a cleaning solution.

5. Both systems are pressurized systems capable of supplying a solution from its reservoir. Both systems use similar fittings of similar materials. Both systems control the water with a switch. The C-1890 can inject pressurized air by a switch. The K962665 does not have this switch for air purging. A shroud covers the tubing and valves of the C-1890 to prevent tampering. A heavy duty reservoir is included in both systems. The C-1890 has a preset air pressure regulator to assure the correct air pressure enters the system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2003

Dr. Thad Overmyer
Anodia Systems
514 South Third Street
Danville, Kentucky 40422

Re: K023896
Trade/Device Name: C-1890
Regulation Number: 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: May 7, 2003
Received: May 9, 2003

Dear Dr. Thad Overmyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

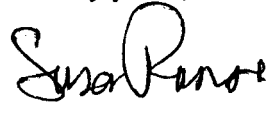
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023896

Device Name: C-1890

Indications for Use:

The C-1890 is designed to clean the dental unit water lines by means of injecting pressurized air and than a solution

(PLEASE DO NOT WIRTE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use
(Per 21 CFR 801.109

(Optional Format 1-2-9)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K023896